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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,180	04/27/2005	Michal Eisenbach-Schwartz	EIS-SCHWARTZ35	5208

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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,180	EISENBACH-SCHWARTZ ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37 and 40-43* is/are pending in the application.

4a) Of the above claim(s) *37,40 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restrictions

Applicant has elected with traverse the invention of Group II, Claims 30-42, drawn to a method for treating a disease which is susceptible to a T-cell- mediated autoimmune disease, wherein said method comprises the use of a pathogenic self- antigen, a peptide of said antigen, or a modified peptide of said antigen.

Within Group II, Applicant has elected the non-autoimmune species "glaucoma", and the antigen species "peptide of SEQ ID NO:5".

Amendments

In the reply filed March 21, 2008, Applicant has cancelled claims 1-36 and 38-39, withdrawn claims 37, 40-41, amended claims 37, 40-42, and added new claims, claim 43.

Claims 37 and 40-41 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claims 42-43 are under consideration.

Priority

This application is a 371 of PCT/IL03/00251, filed March 25, 2003. Applicant's claim for the benefit of a prior-filed application parent provisional application 60/367,271, filed on March 26, 2002 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The disclosure of the prior-filed application, 60/367,271, filed on March 26, 2002, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application, specifically the peptide TSSEAATE (SEQ ID NO:5). Support for the peptide TSSEAATE (SEQ ID NO:5) is found in PCT/IL03/00251, filed March 25, 2003.

Accordingly, the effective priority date of is granted as March 25, 2003. If Applicant believes the earlier applications provide support for this disclosure, Applicant should point out such support by page and line number in the reply to this Action.

Information Disclosure Statement

Applicant has filed an Information Disclosure Statement on September 27, 2004 that has been considered. The signed and initialed PTO Form 1449 is mailed with this action.

The listing of references in the specification (pgs 25-27) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

Examiner's Note

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the March 21, 2008 response will be addressed to the extent that they apply to current rejection(s).

Claim Rejections - 35 USC § 112

1. **The prior rejection of Claims 30-33, 36, 38-39 and 42 under 35 U.S.C. 112, second paragraph, is withdrawn** in light of Applicant's cancellation of and/or amendments to the claims.

Claim Rejections - 35 USC § 112

2. **The prior rejection of Claims 30-33, 36, 38-39 and 42 under 35 U.S.C. 112, first paragraph,** as failing to comply with the written description requirement **is withdrawn** in light of Applicant's amendments to the claims limiting the scope of the immunogenic peptides to the specifically recited genus of SEQ ID NOs in the base claim, Claim 43.

3. **The prior rejection of Claims 30-33, 36, 38-39 and 42 under 35 U.S.C. 112, first paragraph**, **is withdrawn** in light of Applicant's arguments regarding the efficacy of the instantly claimed peptides in protecting the eye, that the CNS injury animal models disclosed in the specification reflect CNS injury in humans, and that experiments in a sufficient number of genetic background variants provides evidence for the general concept of the autoimmune response elicited with the peptides of the claimed invention, for which the Examiner finds persuasive.

Claim Rejections - 35 USC § 102

4. **The prior rejection of Claims 30-32 and 39 under 35 U.S.C. 102(b)** as being anticipated by Kipnis et al (PNAS 97:97(13):7446-7451, 2000), as evidenced by Jiang et al (Cellular Immunol. 217:87-94, 2002) **is withdrawn** in light of Applicant's cancellation of the claims.

5. **The prior rejection of Claims 30-32 and 39 under 35 U.S.C. 102(b)** as being anticipated by Fisher et al (J. Neurosci. 21(1): 136-142, 2001) **is withdrawn** in light of Applicant's cancellation of the claims.

6. **The prior rejection of Claims 30-32, 39 and 42 under 35 U.S.C. 102(b)** as being anticipated by Schori et al (PNAS 98(6):3398-3403, 2001; *of record in IDS), as evidenced by

Jiang et al (Cellular Immunol. 217:87-94, 2002) **is withdrawn** in light of Applicant's cancellation of and/or amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 42-43 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Schori et al (PNAS 98(6):3398-3403, 2001; *of record in IDS) and Singh et al (J. Immunology 152: 4699-4705, 1994; *of record).

Determining the scope and contents of the prior art.

Schori et al teach a method for treating a disease, disorder or injury in the eye, wherein said disease, disorder or injury is other than an autoimmune disease of the eye, the method comprising immunizing an individual with a non-pathogenic Cop-1 peptide that provides highly effective protection from retinal ganglion cell (RGC) death induced by ocular hypertension in the rat model of glaucoma. Cop-1 is protective for optic nerve crush injury and ocular hypertension (pgs 3401-3402).

Schori et al do not teach the non-pathogenic antigen to be from S-antigen, specifically, the instantly elected embodiment TSSEAATE (SEQ ID NO:5). However, at the time of the invention, Singh et al taught that the peptide TSSEAATE (SEQ ID NO:5) could block experimental uveitis (pg 4701, Table 1), and thus may have potential for the treatment of the eye (pgs 4699-4700, joining ¶).

Ascertaining the differences between the prior art and the claims at issue, and Resolving the level of ordinary skill in the pertinent art.

People of the ordinary skill in the art will be highly educated individuals such as medical doctors, scientists, or engineers possessing advanced degrees, including M.D.'s and Ph.D.'s. Thus, these people most likely will be knowledgeable and well-read in the relevant literature and have the practical experience in the pathological basis for retinal diseases and immunology. Therefore, the level of ordinary skill in this art is high.

Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to try substituting the peptide of Schori et al with the peptide of Singh et al for the treatment of an eye disease such as glaucoma because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention, and "a person of ordinary skill has good

reason to pursue the known options within his or her technical grasp. If this leads to the anticipate success, it is likely that product not of innovation but of ordinary skill and common sense." An artisan would be motivated to try substituting the peptide of Schori et al with the peptide of Singh et al for the treatment of an eye disease such as glaucoma because the art has long recognized that intraocular inflammation (uveitis) includes specific diseases such as glaucoma, and thus it would naturally flow that administration of the TSSEAATE (SEQ ID NO:5) peptide capable of blocking uveitis (Singh et al) would also treat a patient suffering from ocular nerve injury or ocular hypertension such as glaucoma.

Thus, the invention as a whole is *prima facie* obvious.

Conclusion

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill, Ph.D./
Examiner, Art Unit 1633

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633